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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/726,880	11/30/2000	Chyi-Cheng Chen	20223 US (C38435/120240)	1470
7590 06/01/2006			EXAMINER	
STEPHEN J. BROWN,ESQ. BRYAN CAVE LLP 1290 AVE. OF THE AMERICAS 33rd floor NEW YORK,, NY 10104			CHANNAVAJALA, LAKSHMI SARADA	
			ART UNIT	PAPER NUMBER
			1615	

DATE MAILED: 06/01/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/726,880

Applicant(s)

CHEN ET AL.

Examiner

Lakshmi S. Channavajjala

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 March 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-15 and 17-27 is/are pending in the application.
- 4a) Of the above claim(s) 16 and 18-27 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-15 and 17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Receipt of amendment and remarks dated 3-06-06 is acknowledged.

Claims 1 and 3-27 have been examined.

Claim 2 has been canceled. Claims 16 and 18-27 have been withdrawn. Claims 1, 3-15 and 17 have been examined.

Response to Arguments

In response to the amendment and applicants' arguments, the following rejection has been withdrawn:

- 1. Rejection of claims 1, 3-15 and 17 were rejected under 35 USC 1112, 2nd paragraph.**
- 2. Rejection of claims 1, 7-11 and 15 are under 35 USC 102(b) as being anticipated by US 5,120,761 to Finnan.**
- 3. Claims 12-14 are rejected under 35 USC 103(a) as being unpatentable over US 5,120,761 to Finnan.**
- 4. Claims 1 and 3-6 are rejected under 35 USC 103(a) as being unpatentable over US 3,971,852 in view of Brenner et al US 5,120,761 to Finnan.**

Applicants have not argued the rejection of claims 1, 3-15 and 17 under the judicially created doctrine of double patenting rejection as being unpatentable over the claims 1-20 of US patent No. 6,162,474. However, in their response dated 3-28-05, applicants agreed to file a terminal disclaimer and therefore the rejection has been maintained.

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Upon careful consideration, examiner has reinstated the following rejection of record:

1. Claims 1 and 7-15 are rejected under 35 USC 103(a) as being unpatentable over EP 841010 ('010) to Tritsch et al (US 6,0171,963 patented to Tritsch et al has been relied upon as a translation of '010).

Tritsch teaches stable, water dispersible preparations of fat soluble substances, which are prepared by preparing an aqueous emulsion of the microbially produced oil that has been stabilized with an antioxidant and fish gelatin (col. 1, lines 32-45). Tritsch teaches adding tocopherol and ascorbyl palmitate, which read on the claimed fat-soluble vitamins. , Tritsch teaches a ratio of 80:20 or 20:80 for the matrix t oily material, which includes the claimed ratios. With respect to the claimed particle size, Tritsch teaches 200 nm in example 1, as opposed to the claimed 80-120 nm. However, Tritsch teaches that upon addition of the oily material to the gelatin matrix, the emulsion step is carried out at atmospheric pressure or elevated pressure up to 1000 bar (100 MPa). Examiner notes that instant specification employs the step of emulsification that is performed at a pressure of 10,000 to 60,000 psi (that is equivalent t 680 t 4080 bar) to obtain a droplet size of 70 to 200 nm (paragraph bridging page 20 and page 21). Thus, the pressure of up to 1000 bar (taught by Tritsch) includes the 680 bar employed by the instant invention. Further, instant specification states that the above range of pressure results in the droplet size that includes the size (200 nm) taught by Tritsch. Therefore, it would have been obvious for one of an ordinary skill in the art at the time of the instant invention to choose an optimum pressure i.e., pressure as much as up to 1000 bar so

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as to achieve a desired particle size. While Tritsch does not teach the lower particle size, absent any criticality of the particle or droplet size, one of an ordinary skill in the art would have readily prepared a pulverous fat-soluble nutritional preparation that possess optimum droplet size for stability, optimal resorption and for water-dispersibility.

2. Claims 1, 3-15 and 17 are rejected under 35 USC 103(a) as being unpatentable over EP 937412 (EP) in view of EP 841010 ('010) to Tritsch et al (US 6,0171,963 patented to Tritsch et al has been relied upon as a translation of '010) or Tritsch in view of EP.

EP teaches preparation of finely divided pulverous carotenoid preparation formed by suspending the active ingredient in an organic solvent, feeding the suspension to a heat exchanger, rapidly mixing with a swellable colloid, removing the solvent and converting the dispersion into a pulverous preparation. Among the colloids, EP teaches gelatin, starch, gums, pectin etc (col. 3, lines 1-7). EP does not teach the claimed particle size and teaches particles of 213, 225 or about 400 nm.

Tritsch, discussed above, Tritsch teaches stable, water dispersible preparations of fat soluble substances, which are prepared by preparing an aqueous emulsion of the microbially produced oil that has been stabilized with an antioxidant and fish gelatin (col. 1, lines 32-45). Tritsch teaches adding tocopherol and ascorbyl palmitate, which read on the claimed fat-soluble vitamins. , Tritsch teaches a ratio of 80:20 or 20:80 for the matrix to oily material, which includes the claimed ratios. With respect to the claimed particle

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size, Tritsch teaches 200 nm in example 1, as opposed to the claimed 80-120 nm.

However, Tritsch teaches that upon addition of the oily material to the gelatin matrix, the emulsion step is carried out at atmospheric pressure or elevated pressure up to 1000 bar (100 MPa). Examiner notes that instant specification employs the step of emulsification that is performed at a pressure of 10,000 to 60,000 psi (that is equivalent to 680 to 4080 bar) to obtain a droplet size of 70 to 200 nm (paragraph bridging page 20 and page 21). Thus, the pressure of up to 1000 bar (taught by Tritsch) includes the 680 bar employed by the instant invention. Further, instant specification states that the above range of pressure results in the droplet size that includes the size (200 nm) taught by Tritsch.

Therefore, it would have been obvious for one of an ordinary skill in the art at the time of the instant invention to choose an optimum pressure i.e., pressure as much as up to 1000 bar, taught by Tritsch in the preparation of the pulverized powder of EP because Tritsch suggests employing up to 1000 bar for achieving a particle size or even lower pressure between 300-500 bars, so as to achieve a desired particle size that renders the preparation stable with optimum dispersibility. While Tritsch does not teach the lower particle size, absent any criticality of the particle or droplet size, one of an ordinary skill in the art would have readily prepared a pulverous fat-soluble nutritional preparation that possess optimum droplet size for stability, optimal resorption and for water-dispersibility. Alternatively, it would have been obvious for one of an ordinary skill in the art at the time of the instant invention to employ materials such as starch, gums, etc., of EP for forming the matrix of Tritsch because EP suggests equivalency

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between gelatin, starch, gum, pectin etc., in their ability to form a swellable colloid matrix. Therefore, a skilled artisan would have expected to achieve matrix with similar properties with any of the swellable colloids of EP.

RESPONSE:

Applicants' previous arguments dated 11-17-03 and 3-28-05; and the declarations dated 3-28-05 have been considered as they are addressed towards the teachings of the presently applied references.

Applicants' arguments regarding the teachings of EP and Tritsch are not persuasive because instant rejections do not include rejection of claims over EP alone and instead are rejected as being unpatentable over EP in view of Tritsch or Tritsch in view of EP. As pointed in the rejections above, Tritsch recognizes employing a pressure of up to 1000 bar, which includes the disclosed pressure (680 bars) of the instant application. With respect to the declaration of Mr. Hermann Stein, while it is true that EP fails to teach particle size lower than 200 nm (at the most 196 nm –see page 5 of the declaration), the teachings of Tritsch have been combined with EP to achieve the claimed particle size because the latter references teaches a pressure of up to 1000 bar that includes the disclosed pressure (680 bar). With respect to the declaration of Dr. Chen, a careful review of the declaration does not reveal the rationale for employing the speed of 4800 in the example (page 4) for preparing the particle size. Further, it stated in the declaration that the method of Tritsch cannot produce particles having an average size of 80 to 200 nm, which is not persuasive because, the very example of Tritsch showed a particle size of 200 nm that is inclusive of the argued range. Further, while

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instant claims only recite 80 to 120 nm and not 70-200 or 80-200 nm, as explained above Tritsch recognizes pressures below 1000 bar for preparing the pulverous powder and instant application states that 680 bar to 4080 bar results in particle size of 70-200 nm. Further, "up to 1000 bar" of Tritsch includes a pressure of 680, which according to instant invention should render the claimed particle size. Furthermore, Tritsch also mentions lower pressure (300-500 bar), which applicants have not shown if it renders in the claimed particle size. Finally, absent evidence to the criticality of the particle size, a difference of 120- 50 nm, from the claimed to that discloses in Tritsch (or EP), it would have been within the scope of a skilled artisan at the time of the instant invention to obtain a suitable particle size so as to render the fat-soluble materials dispersible and achieve optimum resorption, as recognized by Tritsch.

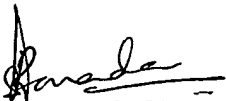
No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lakshmi S. Channavajjala whose telephone number is 571-272-0591. The examiner can normally be reached on 9.00 AM -6.30 PM

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on 571-272-0602. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Lakshmi S Channavajjala
Examiner
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May 30, 2006